

### REMARKS

A check for the requisite fee for a three month extension of time accompanies this response. Any fees that may be due in connection with filing this paper or with this application during its entire pendency may be charged to Deposit Account No. 06-1050. If a Petition for extension of time is required, this paper is to be considered such Petition, and any fee charged to Deposit Account No. 06-1050.

Claims 8-14 and 58-72 are pending in this application. Claim 8 is amended to more particularly point out and further clarify the claimed subject matter. As amended, Claim 8 recites that a change in a phenotype is analyzed in the host cells containing the nucleotide sequence that encodes the product with which a function is associated, and the function is assigned based on the change in the phenotype. Claim 8 as amended also clarifies that the method assigns a gene function corresponding to a particular phenotype in a cell. Support for these amendments are found in the specification, for example, at page 1, lines 8-11; page 3, lines 23-26; page 4, line 32, through page 5, line 2; page 6, lines 4-8; and page 15, lines 3-21.

#### **THE REJECTION OF CLAIMS 8-14 AND 58-72 UNDER 35 U.S.C. §112, Second Paragraph**

Claims 8-14 and 58-72 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter. The Office Action provides two bases for the rejections as follows:

First, the Office Action alleges that the metes and bounds of the claims are vague because in the claimed methods of assigning a function to a product, there is a step of “analyzing phenotypic changes to thereby identify a corresponding change in function,” that implies that the function is already known. The Office Action asserts that in order to identify a “change in function,” the original function must previously be known.

Second, the Office Action alleges that the claims are indefinite because it is not clear that the antisense nucleic acid specifically binds to mRNA transcribed from the target nucleic acid such that inhibition of one of the products of the mRNA is “directly correlated” to a change in phenotype.

Each of the above two bases are discussed in turn below. Reconsideration of the grounds for rejection is respectfully requested in view of the amendments herein and the following remarks.

### Relevant Law

Definiteness of claim language must be analyzed, not in a vacuum, but in light of (1) the content of the particular application disclosure, (2) the teachings of prior art, and (3) the interpretation claims would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. Claims need only "reasonably apprise those skilled in the art" of their scope and be "as precise as the subject permits." *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. den.*, 480 U.S. 947 (1987). The Court in *Orthokinetics, Inc v. Safety Travel Chairs, Inc.*, 1 USPQ2d 1081 (Fed. Cir. 1986) held that a claim limitation requiring that a pediatric wheelchair part be "so dimensioned as to be insertable through the space between the doorframe of an automobile and one of the seats" is definite. The Court stated:

The phrase 'so dimensioned' is as accurate as the subject matter permits, automobiles being of various sizes. As long as those of ordinary skill in the art realized that the dimensions could be easily obtained, § 112, 2d requires nothing more. The patent law does not require that all possible lengths corresponding to the spaces in hundreds of different automobiles be listed in the patent, let alone that they be listed in the claims.

1 USPQ2d at 1088.

When one skilled in the art would understand all of the language in the claims when read in light of the specification, a claim is not indefinite.

Applicant is unaware of any requirement that terms be defined in the claims when one of skill in the art can readily determine the meaning of the term based on the description and definitions provided in the specification. In this respect, applicant is entitled to be its own lexicographer [see, *e.g.*, MPEP 2111.01, "Applicant may be his or her own lexicographer as long as the meaning assigned to the term is not repugnant to the term's well known usage and utilize terms within the claims that are clear from a reading of the specification"]. *In re Hill*, 73 USPQ 482 (CCPA 1947). When applicant has provided definitions in the specification, the claims are interpreted in light of such definition.

35 U.S.C. § 112, second paragraph requires only reasonable precision in delineating the bounds of the claimed invention. The claim language is satisfactory if it reasonably apprises those of skill in the art of the bounds of the claimed invention and is as precise as the subject matter permits. *Shatterproof Glass Corp.v. Libby-Owens Ford Col*, 758 F.2d 613, 624, 225 USPQ 634, 641 (Fed. Cir), *cert dismissed*, 106 S. Ct. 340 (1985).

The amount of detail required to be included in the claims depends on the particular invention and the prior art and is not to be viewed in the abstract, but in conjunction with whether the specification is in compliance with the first paragraph of 35 U.S.C. § 112. If the claims, read in light of the specification, reasonably apprise those skilled in the art of the utilization and scope of the invention, and if the language is as precise as the subject matter permits, the courts can demand no more:

[i]t is not necessary that a claim recite each and every element needed for the practical utilization of the claimed subject matter (*Bendix Corp. v United States*, 600 F.2d 1364, 1369, 220 Ct. Cl. 507, 514, 204 USPQ 617, 621 (1979); *See, also, Carl Zeiss Stiftung v. Renishaw plc*, 20 USPQ2d 1094, 1101).

#### **Analysis**

1) It is alleged that the metes and bounds of Claims 8-14 and 58-72 are unclear because the step of “analyzing phenotypic changes to thereby identify a corresponding change in function” implies that the function already is known. Claim 8 as amended herein no longer recites identification of “a corresponding change in function.” As amended, Claim 8 recites that a function corresponding to a phenotype and associated with a product encoded by the nucleotide sequence of a sample nucleic acid is assigned by analyzing changes in the phenotype to thereby assign the function. Claim 8, thus, recites that assignment of function is based on analysis of the phenotype, which is pre-selected

Basis for this amendment is found in the specification, for example, at page 1, lines 8-11; page 3, lines 23-26; page 4, line 32, through page 5, line 2; page 6, lines 4-8; and page 15, lines 3-21. In particular, the specification describes how to monitor changes in a particular phenotype known to be associated with a cell (*e.g.*, a tumor cell) and assign a heretofore unknown function based on an observed change in the particular phenotype (*see, e.g.*, page 15, lines 14-21; page 15, line 30 to page 16, line 6; and page 16, line 11 to page 17, line 2). For example, if viral titer is the phenotype being analyzed, then a change in viral titer observed upon inhibition of production of a product encoded by a target nucleic acid mRNA would indicate that the function associated with the product encoded by the target nucleic acid sequence is “viral replication.” (page 16, lines 1-5 of the specification). Similarly, if the phenotypic change being monitored upon inhibition of production of a product encoded by the target nucleic acid mRNA is an altered susceptibility of the host cells to drugs, then the

heretofore unknown function associated with the product encoded by the target nucleic acid sequence would be "drug resistance" (page 16, lines 5-6).

Thus, the metes and bounds of Claim 8 as amended herein are clear: by analyzing a phenotypic change in a host cell, a function can be assigned that corresponds to the phenotype and is associated with a product encoded by a target nucleic acid sequence in the host cell. Therefore, Claim 8 and Claims 9-14 and 58-72 dependent thereon are not indefinite because when read in light of the specification, one of skill in the art would understand the metes and bounds of the claims.

2) It is further alleged that Claims 8-14 and 58-72 are indefinite because it allegedly is not clear that the antisense nucleic acid has a "structure" that "causes specific binding" to the mRNA transcribed from the target nucleic acid so that inhibition of one of the products of the mRNA is "directly correlated" to a change in phenotype.

It is respectfully submitted that by following the steps of the method as claimed and as amended herein, one of skill in the art can assign a heretofore unknown function associated with a product encoded by a sample nucleic acid of known sequence. No additional steps or "correlations" are necessary.

First, the antisense nucleic acids encoded by one or more members of the oligonucleotide family are designed to bind to mRNA transcribed from a target nucleic acid molecule containing the nucleotide sequence of the sample nucleic acid (*see, e.g.*, specification at page 4, line 29 to page 5, line 10). As Claim 8 specifies, the nucleotide sequence of the sample nucleic acid is known. Therefore one or more members of an oligonucleotide family designed based on this known sequence will be transcribed into antisense RNA that binds to mRNA transcribed from the target nucleic acid molecule. A property of antisense nucleic acids whose design is based on a known sequence contained in a target nucleic acid molecule is that one or more of them will bind to the known sequence. The specification describes and incorporates by reference methods of designing antisense RNA directed against a known target sequence (DNA or RNA) of interest (*see, e.g.*, page 7, line 32 to page 8, line 23; *see also* Sczakiel, (1997) *Antisense Nucleic Acid Drug Dev.* 7:439-444, entitled "The Design of Antisense RNA," incorporated by reference in the specification and submitted in an Information Disclosure Statement mailed July 19, 2002).

Thus, Claim 8 recites that the sample nucleic acid contained in the target nucleic acid molecule is of known sequence and further specifies that one or more of the oligonucleotide family members expressed as individual transcription products in the host cells encode antisense RNA that binds to mRNA transcribed from the target nucleic acid molecule that contains the (known) nucleotide sequence of the sample nucleic acid. Therefore Claim 8 is clear without having to further specify that the transcription products encoded by the oligonucleotide family (*i.e.*, antisense RNA) have a “structure” that “causes specific binding to the mRNA.”

Furthermore, because the oligonucleotide family is designed to encode antisense RNA (transcription products) that binds to mRNA encoded by the known sample nucleic acid sequence of interest, and Claim 8 specifies such property, one then can look for instances where expression of the (antisense RNA) transcription product, which would bind to the mRNA according to the recited properties set forth in Claim 8, inhibits production of a product of the mRNA (*see, e.g.*, definition at page 5, lines 13-14 of the specification, where “antisense RNA” is defined as an RNA molecule that binds to a target nucleic acid molecule, thereby, inhibiting its function and the expression of the encoded product).

In the resulting host cells (that exhibit inhibition of production of a product of the mRNA), one then only has to identify any changes in phenotype. Because the method looks for functions corresponding to particular phenotypes, the original phenotype is known, and one looks for a change in this known phenotype. The change in phenotype does not have to bear a “direct correlation” to the inhibition of expression; it is sufficient that both are observed in the same host cells, *i.e.*, inhibition of production of a product of the mRNA by binding of antisense RNA directly or indirectly leads to a change in the phenotype of the cells. The change in phenotype may then be used to assign a function corresponding to the phenotype and associated with the product encoded by the nucleotide sequence of the sample nucleic acid. Each of these steps are set forth in Claim 8 as amended herein and fully define the method as disclosed in the specification.

The steps of the method as set forth and described in the specification are as follows:

(1) introduction of an oligonucleotide family into recombinant non-bacterial host cells having a particular phenotype and amplification and expression of one or more members therein (*see, e.g.*, page 3, lines 13-26);

(2) the oligonucleotide family is designed so that the members encode antisense RNA that binds to mRNA coded for by a target nucleic acid molecule containing a known nucleic acid sequence of interest encoding the product for which a function is to be assigned (*see, e.g.*, page 4, line 29 to page 5, line 10);

(3) monitoring inhibition of production of a product of the mRNA (*see, e.g.*, page 15, line 30 to page 16, line 6; page 16, lines 20-23); and

(4) in the resulting host cells, identifying a change in the phenotype to thereby assign a function corresponding to the phenotype and associated with a product encoded by the known nucleic acid sequence of interest (*see, e.g.*, page 15, lines 3-23).

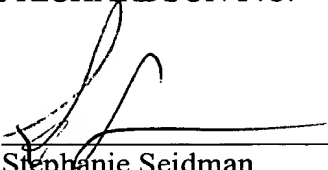
Because each of the above steps are recited in Claim 8 as amended herein, it is respectfully submitted that Claim 8 and Claims 9-14 and 58-72 dependent thereon are definite.

\* \* \*

In view of the above amendments and remarks, reconsideration and allowance of the application are respectfully requested.

Respectfully submitted,  
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